



Customer No.: 07278

Docket No.: 01946/100B035-USD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Andrea Leone-Bay et al.

Serial No.: 10/623,142

Filed: July 18, 2003

For: COMPOUNDS AND COMPOSITIONS FOR DELIVERING AGENTS

September 16, 2004

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed: (Check one of the boxes A-D)

- A. Within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.
- B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- C. after (A) and (B) above, but before the mailing date of a final rejection, a notice of allowance, or any other action that closes prosecution, and Applicants have made

Docket No. 01946/100B035-USD

the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- i. Counsel states that, upon information and belief, each item of information listed herein was either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ii. A check for the fee set forth in 1. 17(p), presently believed to be \$180, is enclosed.

D. after (A), (B) and (C) above, but before payment of the issue fee: Counsel states that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the IDS; or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

- i. A check for the fee set forth in 1.17 (p), presently believed to be \$180, is enclosed.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.).

- A. Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.
- B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:
[SERIAL NO. & FILING DATE].

Applicant identifies these documents by attaching hereto copies of the forms PTO-892 and PTO/SB08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

[X] 3. Document CC is not in the English language. In accordance with 1.98(c), Applicant states:

- An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application is enclosed.
- A concise explanation of the relevance of document CC is found in the attached search report (see MPEP § 609 A(3)x).
- A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- A concise explanation of document(s) _____ can be found on the attached sheet.

4. No explanation of relevance is necessary for documents in the English language (see MPEP § 609 A(3)).

[X] 5. Other information being provided for the examiner's consideration follows:

A European Search Report, dated August 25, 2004, which issued during the prosecution of European Patent Application No. EP 96 91 3778.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless other-wise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

CROSS REFERENCE UNDER 37 C.F.R. §1.78 TO RELATED APPLICATIONS

Pursuant to 37 C.F.R. § 1.78, Applicant notes that the above-identified patent application may be related to the following U.S. Patent Applications:

(1) U.S. Patent Application Serial No. _____, filed _____.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

September 16, 2004

5 Jay P. Lessler
Registration No. 41,151
Attorney for Applicants *44085*

DARBY & DARBY P.C.
805 Third Avenue
New York, N.Y. 10022
(212) 527-7700



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete If Known	
				Application Number	10/623,142-Conf. #5198
				Filing Date	July 18, 2003
				First Named Inventor	Andrea Leone-Bay
				Art Unit	1615
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	01946/100B035-USD

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
AA**	US-3,489,793-B1	01-13-1970	Bertelli		
AB**	US-4,613,618-B1	09-23-1986	Choay et al.		
AC**	US-3,931,153-B1	01-06-1976	Schmidt et al.		

**Pursuant to the Notice issued by the United States Patent and Trademark Office dated July 11, 2003 waiving the requirements of 37 C.F.R. § 1.98(a)(2)(i), a copy/copies of the United States Patent on PTO/SB08 is/are not being submitted.

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
BA	WO-94/23767-A1		10-27-1994	Emisphere Technologies, Inc.	T ⁶

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	CA	Milstein, Sam, "Oral Bioavailability of Partially Folded Proteins", Proceedings of the 1995 Miami Bio/Technology Winter Symposium, Advances in Gene Technology: Protein Engineering and Structural Biology, Short Reports, Vol. 6, February 4-9, 1995, p. 13.			
	CB	Ibrahim, El Sebai A., et al., "Synthesis of 4-Substituted Aminobenzoate Quaternary Salts and Potent Antispasmodic Agents", Journal of Pharmaceutical Sciences, American Pharmaceutical Association, Vol. 68, No. 3, March 1979, pp. 332-335.			
	CC	Picciola, G., "Sintesi Di Acidi Chinazolinonici e Benzossazinonici e Studio Delle Loro Proprietà Antinfiammatorie", Farmaco, Edizione Scientifica, Vol. 31, No. 9, 1976, pp. 655-664.			
	CD	Jorgensen, Eugene C., et al., "Angiotensin II analogs. IV. Synthesis and Biological Evaluation of Simplified Angiotensins", Journal of Medicinal Chemistry, Vol. 13, No. 4, 1970, pp. 744-745.			
	CE	Leone-Bay, Andrea, et al., "N-Acylated α -Amino Acids as Novel Oral Delivery Agents for Proteins", Journal of Medicinal Chemistry, Vol. 31, No. 21, 1995, pp. 4263-4269.			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

09/17/04

1FW

Application No. (if known): 10/623,142

Attorney Docket No.: 01946/100B035-USD



Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. *CV367696855-US* in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on September 16, 2004
Date


Signature


Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Information Disclosure Statement (4 pages)
PTO SB/08 (1 page)
6 Documents
Copy of European Search Report
Return Postcard